

Application No. 10/031,752
Response filed December 17, 2003
Reply to Office Action dated September 17, 2003

REMARKS

The present application is directed to methods and compositions comprising mycobacterial cell wall extract for activating the immune system of an animal and enhancing production performance of the animal. In a preferred embodiment, the methods of the present invention involve the administration of compositions comprising mycobacterial cell wall extract from *Mycobacterium phlei*.

In an effort to facilitate prosecution, the specification has been amended and the following remarks are provided in response to the rejections raised in the September 17, 2003 Office Action. No new matter has been added and support for the amendments is found throughout the specification.

Specification

In the September 17, 2003 Office Action, the Examiner noted that a statement reciting the claim of benefit of priority to provisional application 60/145,314 must be recited on page 1 of the specification. Applicant has herein amended the specification pursuant to the Examiner's request. Applicant has also amended the specification reciting a claim of priority to International Patent Application No. PCT/US00/20013 filed on July 21, 2000.

The Examiner also stated that the application does not contain an abstract of the disclosure as required by 37 C.F.R. §1.72(b). Applicant has herein amended the specification pursuant to the Examiner's request.

Double Patenting

In the September 17, 2003 Office Action, the Examiner rejected Claims 32-53 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-19 of United States Patent No. 5,759,554 (hereafter '554). The Examiner stated that although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims encompasses methods of stimulating the immune system of an animal comprising administering a mycobacterial cell wall extract. In an effort to facilitate

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prosecution, Applicants agree to submit a terminal disclaimer once the claims are considered to be allowable. Accordingly reconsideration and withdrawal of the claim rejections based on the judicially created doctrine of obviousness-type double patenting is respectfully requested.

In addition the Examiner rejected Claims 32-53 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-5 of United States Patent No. 5,632,995 (hereafter '995). The Examiner stated that although the conflicting claims are not identical, "they are not patentably distinct from each other because each set of claims encompasses methods of increasing reproductive performance of an animal comprising administering a mycobacterial cell wall extract prior to ovulation." Applicants respectfully traverse.

Applicants respectfully submit that the '955 patent recites claims directed to a method of increasing reproductive performance in a human or animal comprising administering to the human or animal an amount of a nonspecific immunostimulant prepared from a bacterial cell wall extract effective to increase the reproductive performance of the human or animal. The '955 patent defines "reproductive performance" as "an increase in number of offspring, an increase in survival rate of offspring, an increase in first service conception rate and a decrease in service number per conception" (see column 1, lines 19-24). In contrast, the present claims are directed to methods for enhancing production performance defined by the specification as "an increase in the average daily weight gain of an animal, a decrease in the mortality of an animal, a decrease in the number of treatment days necessary to maintain the health of an animal, a decrease in the cost of treatment necessary to maintain the health of an animal and any combination thereof" (see page 7, lines 12-16). Applicants respectfully submit that based on the teachings of the specifications, and based on the level of knowledge of one skilled in the art, one would not expect that methods for "enhancing production performance" and methods for "increasing reproductive performance" would be interchangeable or even related. Furthermore, '955 fails to teach or even suggest that the methods therein would be applicable for enhancing production performance. Accordingly, Applicants respectfully request that the rejection of

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Claims 32-53 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of United States Patent No. 5,632,995, be removed.


Conclusion

For at least the above reasons, Applicants respectfully request allowance of Claims 32-53 and issuance of a patent containing these claims in due course. If there remain any additional issues to be addressed, the Examiner is urged to contact the undersigned attorney.

The foregoing is submitted as a full and complete response to the Office Action mailed September 17, 2003. Applicants respectfully submit that the claims are fully enabled, novel and non-obvious over the cited art. Applicants assert that the claims are now in condition for allowance and respectfully request that the application be passed to issuance. If the Examiner believes that any informalities remain in the case, which may be corrected by Examiner's amendment, or that there are any other issues which can be resolved by a telephone interview, a telephone call to the undersigned attorney at (404) 745-2463 is respectfully solicited.

Respectfully submitted,

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